REMARKS

Claims 1 to 40, as amended, appear in this application for the Examiner's review and consideration. Claims 8-28 have been withdrawn from consideration, as being drawn to non-elected subject matter. Claims 1-7 and 29-38 are currently rejected. Claims 1-6 and 29-34 have been amended, and claim 7 has been canceled. Support for the amendments can be found in the specification on page 6, lines 13-19 and claim 7 as originally filed. Claims 39 and 40 are newly added, support for which can be found in the specification on page 13, lines 1-5, in table 1 and on page 16, in table 2. Further, submitted herewith is a declaration by Claude Singer regarding comparative results for Lansoprazole obtained according to the Kato et al reference (U.S. 6,002,011).

1. Claims 1-7 and 29-38 are rejected under 35 U.S.C. 102(a), (b) and/or (e) as being anticipated.

The Examiner has rejected claims 1-7 and 29-38 as being anticipated by Vercer et al., Kotar et al., Choi et al., Nohara et al., Kato et al., and Avrutov et al. I, and II for the reasons set forth in the previous Office Action. According to the Examiner the cited references specifically disclose the claimed compound and compositions. Further, the Examiner asserts that she is well aware that applicants are not claiming polymorphs but that the stable compound is very similar to polymorphs. In addition, the Examiner refers to Choi et al asserting that the reference recites a compound free of impurities.

In response, and in addition to Applicants previous arguments, Applicants submit that, as recited in claims 1 to 6, the presently claimed invention is directed to a chemically stable lansoprazole, either comprising between 500 ppm to 3000 ppm water, 300 ppm and 5000 ppm alcohol or a combination thereof, or comprising less than 0.1% of both the sulfone and sulfide degradation products, after at least 6 months at 2-8°C or at 25°C and 60% relative humidity, which may be prepared by the process of the invention. As recited in claims 29-38, the presently claimed invention is directed to a pharmaceutical composition comprising such chemically stable lansoprazole.

In contrast to the Examiner's assertions the claimed invention is not to a chemically pure substance or a particular crystalline polymorph thereof but to a stable lansoprazole which contains water and/or alcohol in the recited ranges as described in the specification and is stable for at least 6 months at 2°C to 8°C or at 25°C and 60% relative humidity. The

present claims and the specification are clearly not directed to only chemically pure substances. Instead, as originally filed, each of the claims requires that the claimed stable lansoprazole compound further comprises at least a specified amount of water and/or a specified amount of alcohol as discussed in applicants previous responses. Further, the specification also clearly teaches that the stable lansoprazole compound of the invention may include other impurities in addition to water and alcohol as discussed in applicants previous responses. Thus, in the present case, in light of the specification and the originally filed claims, one of ordinary skill in the art will understand that Applicants have elected to define "lansoprazole" to mean lansoprazole containing residual process water and/or alcohol and one or more impurities.

In addition, Applicants submit that although the cited prior art references may disclose lansoprazole and polymorphs of lansoprazole, the references disclose non-stable, prior art lansoprazole, not the presently claimed chemically stable lansoprazole. Applicants submit that, as recited in claim 1, the presently claimed invention is directed to a chemically stable lansoprazole, comprising greater than 500 ppm and not more than about 3,000 ppm water; as recited in claim 3, the presently claimed invention is directed to a chemically stable lansoprazole comprising greater than 200 ppm and not more than about 5,000 ppm alcohol; and as recited in claim 5, the presently claimed invention is directed to a chemically stable lansoprazole comprising greater than 500 ppm and not more than about 3,000 ppm water, and greater than 200 ppm and not more than about 5,000 ppm alcohol. Applicants also submit that, as recited in claim 29 to 38, the presently claimed invention is directed to pharmaceutical compositions, comprising the chemically stable lansoprazole of claims 1, 3, and/or 5 and a pharmaceutically acceptable excipient.

As demonstrated in Examples 2 and 3 and Tables 1 and 2 of the present specification, the presently claimed lansoprazole is chemically stable and is substantially more chemically stable than prior art lansoprazole. The presently claimed lansoprazole is stable for at least about 6 months at either 2°C to 8°C or at 25°C and 60% relative humidity as shown in Table 1. After three months at 40°C and a relative humidity of 75 percent, the stable lansoprazole of the invention contains only 0.02 percent of the sulfide compound and 0.03 percent of the sulfone compound, and remains white. In contrast, under the same conditions, the non-stabilized, prior art lansoprazole contains 0.04 percent of the sulfide compound and 0.06 percent of the sulfone compound, and has changed color. Further, as shown in the Singer

declaration, submitted herewith, lansoprazole prepared according to Kato et al is substantially less stable than the claimed lansoprazole. The results in the Singer declaration show that after three months at a temperature of 40°C and a relative humidity of 75 percent, lansoprazole prepared both according to example 1 and comparative example 1 as in the Kato et al reference (US 6,002,011), contain 0.14% (w/w) or 0.17% (w/w) of the sulfone impurity and 0.14% (w/w) or 0.34% (w/w) of the sulfide impurity respectively, showing an increase in impurities upon storage, and show a brownish discoloration. Therefore, as observed in the Singer declaration lansoprazole as in the Kato et al reference lacks the stability of lansoprazole as in the claimed invention.

Moreover, in contrast to the presently claimed invention, Vrečer and Kotar disclose the relative physical stability of polymorphic forms A and B of prior art lansoprazole. In particular, Vrečer discloses that lansoprazole polymorphic form B is not physically stable, and transforms to polymorphic form A on heating. Vrečer and Kotar disclose only non-stable, prior art lansoprazole, and, thus, neither reference discloses a chemically stable lansoprazole as presently claimed as neither Vrečer or Kotar stabilizes its crystalline lansoprazole to provide chemically stability. Therefore, Vrečer and Kotar do not anticipate the present claims.

Choi discloses a process for preparing conventional prior art sulfoxide compounds, such as lansoprazole, comprising oxidizing a sulfide compound with hydrogen peroxide in the presence of a rhenium catalyst. The disclosed process reportedly minimizes the production of N-oxide and sulfone byproducts. Page 1, lines 4 to 17. The m-chloroperbenzoic acid, used in the prior art as the oxidizing agent, reportedly results in the formation of the N-oxide and sulfone byproducts, resulting in a low yield in the preparation. Page 3, lines 9 to 22. Other prior art processes, such as the oxidation of the sulfide compound with hydrogen peroxide in the presence of a vanadium catalyst, reportedly result in the production of more than 1 HPLC area percent of the sulfide compound and a product containing 0.4% of such compound after purification. Page 6, lines 2 to 9, and page 7, lines 1 to 11. The disclosed process reportedly minimizes the production of the N-oxide and sulfone by products, and removes the by products by filtration.

Applicants submit that although Choi discloses a lansoprazole having a reported purity of 99.95%, Choi discloses a non-stable, albeit a very pure prior art lansoprazole, and, thus, does not disclose the chemically stable lansoprazole composition of the presently

claimed invention, being stable for at least 6 months at 2°C to 8°C or at 25°C and 60% relative humidity. The presently claimed stable lansoprazole is obtained wherein a final purification step involves the use of ammonia. The use of ammonia results in the stabilization of the claimed lansoprazole as can be seen by the results provided in Table 2 wherein lansoprazole prepared using ammonia is stable whereas lansoprazole not prepared using ammonia is not stable. Therefore, as Choi discloses a conventional lansoprazole, not the chemically stable lansoprazole of the present invention, the present claims directed to chemically stable lansoprazole, which is stable for at least 6 months at 2°C to 8°C or at 25°C and 60% relative humidity, are not anticipated by Choi.

Nohara discloses 2-[2 pyridylmethylthio-(sulfinyl)-] benzimidazoles and processes for preparing such compounds. A sulfide derivative, prepared with the disclosed process, can be oxidized to prepare a sulfinyl derivative. Column 2, lines 21 to 48. Compounds produced with the disclosed process "can be isolated and purified by conventional means, e.g., crystallization and chromatography." Column 2, lines 66 to 68.

Nohara discloses only non-stable, prior art lansoprazole, and, thus, does not disclose the presently claimed chemically stable lansoprazole which is stable for at least 6 months at 2°C to 8°C or at 25°C and 60% relative humidity. Therefore, the present claims are not anticipated by Nohara.

Kato discloses a prior art substantially solvent-free lansoprazole that is free of decomposition in the course of vacuum drying. Column 2, lines 22 to 26. Kato specifically teaches that

> It is understood that the water content of the substantially solvent-free crystals according to the present invention is not higher than about 500 ppm, preferably not higher than about 300 ppm, and, for still better results, not higher than about 200 ppm, and the alcohol (e.g. ethanol) content is not higher than about 200 ppm, preferably not higher about 100 ppm, and, for still better results, not higher about 80 ppm. Column 7, lines 24 to 30.

Therefore, Kato does not disclose or suggest a stable lansoprazole composition, comprising chemically stable lansoprazole and greater than 500 ppm and not more than about 3,000 ppm water and/or greater than 200 ppm and not more than about 5,000 ppm alcohol, which is stable upon storage for at least 6 months at 2°C – 8°C or at 25°C and 60% relative humidity as presently claimed. Further, the Examiner's reference to claim 7 merely confirms that Kato does not disclose the claimed lansoprazole considering that in Kato claim 7, as

dependent from claim 1, requires less than 500ppm water and less than 200 ppm alcohol, which is clearly different from the presently claimed lansoprazole having greater than 500ppm and not more than 3000ppm water and/or greater than 200ppm and not more than 5000ppm alcohol.

In addition, as observed by Singer in the Singer declaration the results described therein show that lansoprazole prepared according to Kato is not stable upon storage. In the Singer declaration data are presented wherein lansoprazole prepared according to Example 1 and Comparative Example 1 are stored for three months at 40°C and 75% relative humidity. Upon storage the lansoprazole prepared according to Kato shows an increase in the amount of impurities particularly in the sulfide impurity and also shows discoloration from an initially white material to a brownish material. As discussed above in the claimed stable lansoprazole such increase in impurities is not observed nor is a discoloration observed. Accordingly, Kato does not disclose the presently claimed chemically stable lansoprazole, and, thus, Kato does not anticipate the present claims.

Avrutov discloses processes for preparing substituted 2-(2-pyridylmethyl)sulfinyl-1-H-benzimidizoles. Avrutov I and II, page 1, paragraph [0002]. In particular, Avrutov discloses a selective oxidation process for preparing lansoprazole. Avrutov I, page 2, paragraph [0016]; Avrutov II, page 2, paragraph [0025].

Similarly to the reasoning in Choi, Avrutov discloses only non-stable, prior art lansoprazole, not stable for at least 6 months at 2°C to 8°C or at 25°C and 60% relative humidity. Therefore, Avrutov does not disclose the presently claimed invention, and the present claims are not anticipated by Avrutov.

Therefore, as none of Vrečer, Kotar, Choi, Nohara, Kato, and Avrutov disclose the presently claimed invention of chemically stable lansoprazole which is stable for at least 6 months at 2°C to 8°C or at 25°C and 60% relative humidity, the present claims are not anticipated by those references. Accordingly, it is respectfully requested that the Examiner withdraw the rejection of claims 1 to 7 and 29 to 38 under 35 U.S.C. §102(a), (b), and/or (e).

2. Claims 1-7 and 29-38 were rejected under 35 U.S.C. 103(a) as being obvious.

The Examiner has rejected claims 1-7 and 29-38 as being obvious over the combined teachings of Vercer et al., Kotar et al., Choi et al., Nohara et al., Singer et al., Kato et al., and Avrutov et al. I, and II in view of Hableblian et al., Chemical & Engineering News, US

Pharmacopeia, Muzaffar et al, Jain et al, Taday et al, Concise Encyclopedia Chemistry and Brittain et al. (Polymorphism in Pharmaceutical Solids, pages 1-2, 185). Again, according to the Examiner the cited primary references teach the stable crystal forms of the instant known compound and as well as the pharmaceutical compositions. In addition, the Examiner asserts that the remaining references teach that compounds exist in different crystalline forms and that at any particular temperature and pressure only one crystalline form is thermodynamically stable. The Examiner alleges that hence the claimed crystalline form as well as its relative selectivity of properties vis-à-vis the known compound are suggested by the references. According to the Examiner it is obvious in view of the references that the compound would exist in different stable crystalline forms.

In response, Applicants submit that the claimed invention is directed to a chemically stable lansoprazole whether crystalline or not. The method of preparing the chemically stable lansoprazole, presently claimed, contains a crystallization step. However, the claimed invention is not directed to its crystallinity but to a chemically stable lansoprazole. The chemical stability of lansoprazole as in the claimed invention is obtained using a substantial amount of ammonia in a final purification step not taught or suggested in the cited references. Lansoprazole is chemically instable because of its inclusion of solvent (such as water) when crystallized. Not whishing to be bound by any theory, the chemically instability of solvated lansoprazole is attributed to proton attack of lansoprazole at the sulfur atom resulting in the appearance of its derivatives, the sulfide derivative 2-[[3-methyl-4-(2,2,2-trifluorethoxy)-2-pyridinil]thio]-1H benzimidazole and the sulfone derivative 2-[[3-methyl-4-(2,2,2-trifluorethoxy)-2-pyridinil]sulfonyl]-1H benzimidazole, which are considered impurities.

The presently claimed invention is directed to lansoprazole which is stable for at least 6 months at 2°C to 8°C or at 25°C and 60% relative humidity, i.e. is less prone to chemically instability, either comprising 500 ppm to 3000 ppm water, 300 ppm and 5000 ppm alcohol or a combination thereof, and the specification specifically discloses the claimed compound and compositions. None of the cited references, taken alone or in combination, disclose or suggest the chemically stable lansoprazole of the presently claimed invention which is stable for at least 6 months at 2°C to 8°C or at 25°C and 60% relative humidity. Moreover, in examples 1 and 2 of the current specification Applicants provide objective evidence of the unexpected stability of the claimed lansoprazole over unstable prior art lansoprazole, prepared by a different process. In addition, the Singer declaration, submitted herewith,

further provides evidence that the lansoprazole obtained according to the process in the Kato reference fails to show the same stability.

As discussed previously, on page 20 of Applicants' response of September 14, 2006, the Singer et al reference is not a prior art reference. In addition, Avrutov I and II are prior art under 102(e) only and the invention described in Avrutov and the currently claimed invention are commonly owned. For, this reason Avrutov I and II are not available as prior art under 35 U.S.C. §103(a).

Further, as discussed above, Vrečer and Kotar disclose the relative physical stability of polymorphic forms A and B of lansoprazole. In particular, Vrečer and Kotar disclose that lansoprazole polymorphic form B is not physically stable, and transforms to polymorphic form A on heating. However, Vrečer and Kotar do not disclose or suggest a chemically stable lansoprazole as presently claimed which is stable for at least 6 months at 2°C to 8°C or at 25°C and 60% relative humidity.

Choi discloses a process for preparing conventional prior art sulfoxide compounds, such as lansoprazole, comprising oxidizing a sulfide compound with hydrogen peroxide in the presence of a rhenium catalyst as opposed to the process described in the current application of using a substantial amount of ammonia in a final purification step to obtain a stable lansoprazole. Choi discloses only non-stable, prior art lansoprazole, produced with the disclosed process, and, thus, does not disclose or suggest the presently claimed chemically stable lansoprazole, which is stable for at least 6 months at 2°C to 8°C or at 25°C and 60% relative humidity.

Nohara discloses benzimidazoles and processes for preparing such compounds. The disclosed compounds are not the chemically stable lansoprazole composition of the presently claimed invention. Instead, Nohara discloses only non-stable, prior art, lansoprazole. Therefore, Nohara does not disclose or suggest the presently claimed chemically stable lansoprazole, which is stable for at least 6 months at 2°C to 8°C or at 25°C and 60% relative humidity.

Kato discloses a substantially solvent-free lansoprazole that is free of decomposition in the course of vacuum drying. Kato does not disclose or suggest a lansoprazole, having chemical stability over three to six months, as does the presently claimed chemically stable lansoprazole. The 0.03 moles of ammonia per mole of lansoprazole used in the Kato examples is only a trace amount, and is not sufficient to provide a chemically stable

lansoprazole. As discussed above and at page 2 of the present specification, the lansoprazole prepared by the processes disclosed by Kato will be chemically unstable. In fact, as observed by Singe the results described in the Singer declaration show that in the lansoprazole of Kato (prepared according to the processes in example 1 and comparative example 1), stored for three months at 40°C at 75% relative humidity, increased amount of the impurities can be detected. In particular, an increased amount of the sulfide impurity can be detected. The Singer declaration also shows that the lansoprazole of Kato shows discoloration, another sign of decomposition and instability, upon storage for three months at 40°C at 75% relative humidity. The stored lansoprazole obtained according to Kato showed brownish discoloration upon storage. Therefore, Kato does not teach or suggest the presently claimed chemically stable lansoprazole, which is stable for at least 6 months at 2°C to 8°C or at 25°C and 60% relative humidity.

As stated in the Office Action at page 4, Hableblian, Muzaffar, Jain, and Taday each teach that some crystalline compounds can exist in different crystalline forms. The Office Action also states, at page 4, that C & E News, Muzaffar, U.S. Pharmacopia, and Concise Encyclopedia of Chemistry all teach that, at any particular temperature and pressure, only one crystalline form is thermodynamically stable.

However, as discussed above, the presently claimed invention is directed to a chemically stable lansoprazole, not a thermodynamically stable polymorphic form. None of the cited references whether taken alone or in combination, disclose or suggest the presently claimed chemically stable lansoprazole, which is stable for at least 6 months at 2°C to 8°C or at 25°C and 60 relative humidity. Instead, the cited prior art references discloses only non-stable, prior art lansoprazole.

Therefore, as the cited references, whether taken alone or in combination do not disclose or suggest the presently claimed invention, the claims are not obvious over these references. Accordingly, it is respectfully requested that the Examiner withdraw the rejection of claims 1 to 7 and 29 to 38 under 35 U.S.C. §103(a).

3. Claims 29-38 were rejected under 35 U.S.C. 112, first paragraph.

Claims 29 to 38 were rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement, for the reasons set forth on pages 5 to 7 of the Office Action.

In particular, the rejection is based on the possibility of a change in polymorphic state of a crystalline form of a compound during storage or tablet preparation. The Office Action, at page 5, states

> The specification lacks description of how the pharmaceutical composition can be prepared in order to maintain the particular compound of a particular form with the particular infrared and x-ray diffraction being claimed .... Disclosure of x-ray diffraction patterns for the compounds and pharmaceutical compositions comprising the polymorphic forms are lacking in the specification. The specification has also not described how the stable form and composition's being claimed will be maintained and prevented from converting to other forms .....

Further, according to the Examiner, "Applicants merely assert that the instant compounds are not polymorphs. However, the instant compounds behave similar to polymorphs." Moreover, the Examiner asserts that "contra to applicants' arguments ..... the specification lacks description and enablement that the pharmaceutical compositions contain the "stable form" without transformation."

In response, Applicants again respectfully submit that XRD and IR spectra are not provided, and there is no teaching in the specification on how to maintain a particular polymorphic form because a new polymorphic crystalline form of lansoprazole is not disclosed or claimed in the present application. Chemically stability of a compound, here lansoprazole is different from crystalline stability of a particular polymorph and the Examiner's assertion that they behave the same is unfounded. It is known that polymorphic forms may change in processing into a pharmaceutical composition, particularly as where such processing involves some form of preparing a solution considering that polymorphic forms loose there crystallinity in solution. This does not apply to chemically stability as it is not the crystalline form that provides the chemically stability. The presently claimed invention is directed to a chemically stable lansoprazole, which is stable for at least 6 months at 2°C to 8°C or at 25°C and 60% relative humidity. That is, the presently claimed invention is a lansoprazole, produced in a known process, that is then stabilized with the method of the invention, providing the chemically stable lansoprazole of the invention. As the present claims are not directed to a new polymorphic crystalline form, no XRD or IR spectral data are required. No disclosure of how to prevent the lansoprazole of the invention from converting to a different polymorphic form is provided, because the invention is not directed to a polymorphic form.

At pages 1 to 3, the present specification discusses the instability of prior art lansoprazole. As will be understood by one of ordinary skill in the art, the instability of lansoprazole discussed in the specification is not a polymorphic instability. Instead, the instability discussed in the specification is a chemical instability, the conversion of the lansoprazole compound to other chemical compounds such as its sulfide or sulfone derivative. When prior art lansoprazole is stored or exposed to heat and humidity over a period of time, a chemical change occurs, producing impurities in the form of different chemical compounds, which is unrelated to whether or not different polymorphic forms can be obtained if any. At page 3, lines 2 to 12, the present specification states that during storage, prior art lansoprazole degrades, such that the concentration of lansoprazole decreases, resulting in discoloration. Contrary to the Examiner's assertions, this chemical change that may occur is very different from the (structural) change that may occur when processing a chemical compound in preparing a pharmaceutical composition. Thus, degradation of a compound results from a chemical change, not a change in polymorphic form, as alleged in the Office Action.

Moreover, the present specification clearly teaches one of ordinary skill in the art how to make and use the invention, and the specification describes the claimed subject matter in such a way as to reasonably covey to one skilled in the relevant art that the Applicants had possession of the claimed invention at the time the application was filed.

In the first paragraph of the Detailed Description on page 7, the specification discloses the impurities that are formed in lansoprazole during storage. The impurities are further disclosed in Tables 1 and 2 on pages 13 and 16 of the specification, respectively. Processes for preparing the presently claimed chemically stable lansoprazole are set forth in both the Summary and Detailed Description sections of the specification, and are particularly exemplified in Examples 2 and 3 on pages 12 to 14 of the specification. The superior chemical stability of the presently claimed chemically stable lansoprazole, compared to prior art lansoprazole, is set forth in the aforementioned Tables 1 and 2.

Clearly, one of ordinary skill in the art would understand how to make and use the presently claimed invention from the present specification.

With respect to an alleged lack of description as to whether the pharmaceutical carriers are able to maintain the presently claimed chemically stable lansoprazole in the stable form claimed, one of ordinary skill in the art, from the present specification, would

understand how to make and use the presently claimed pharmaceutical compositions. Pharmaceutical carriers, diluents, disintegrates, binders, glidants, dyes, colorants, lubricants, excipients, and the like, useful in the invention, are set forth on pages 9 to 12.

Therefore, as the presently claimed invention is not directed to stable polymorphs, but, instead, is directed to a chemically stable lansoprazole, the present specification clearly teaches one of ordinary skill in the art how to make and use the claimed invention, and, thus, the claims meet the requirements of 35 U.S.C. §112, first paragraph. Accordingly, it is respectfully requested that the Examiner withdraw the rejection of claims 29 to 38 under 35 U.S.C. § 112, first paragraph.

4. Claims 1-7 and 29-38 were rejected under 35 U.S.C. 112, second paragraph for being indefinite.

Claims 1-7 and 29-38 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for the reasons set forth on pages 7-9 of the Office Action.

According to the Examiner, the expression "comprising" and "further comprising" in claims 1-7 and 29-38 are open ended and allow for the inclusion of other parameters not contemplated by Applicant. Applicants understand this to mean that a compound has a specific structure that cannot be modified without changing the compound to a different compound. The Examiner has apparently defined the claimed stable lansoprazole as chemically pure lansoprazole.

In response, as discussed above, Applicants submit and reiterate that one of ordinary skill in the art would understand that any given sample of the active pharmaceutical ingredient lansoprazole contains lansoprazole and some amount of impurities. One of ordinary skill in the art would understand that it is virtually impossible for any given sample of lansoprazole to be 100 percent pure lansoprazole. Instead, a sample of lansoprazole also contains lansoprazole and trace amounts of water and/or alcohol, in addition to trace amounts of other impurities, and, thus, is effectively a lansoprazole composition, even where the lansoprazole is of a very high purity. Even with the presently claimed stable lansoprazole, it is practically impossible to remove all impurities, although the rate at which the amount of any impurities in the presently claimed stable lansoprazole increases is significantly slower during storage than the rate at which impurities are formed in prior art lansoprazole. For these reasons and for the reasons discussed on page 8 and 9 of Applicants previous response

of July 13, 2007, one of ordinary skill in the art would understand that the "stable lansoprazole" of the present invention, as recited in the originally filed claims, is actually a chemically stable lansoprazole that contains trace amounts of impurities, such as the water and alcohol recited in claims 1, 3, and 5 and the sulfone and sulfide derivatives recited in claims 6 and 34. It would also be understood by one of ordinary skill in the art that any bulk sample of lansoprazole would most likely also contain at least trace amounts of impurities other than those recited in the claims. Accordingly, Applicants did contemplate the inclusion of other parameters not recited in the claims. Thus, the present claims are open ended, but still meet the requirements of 35 U.S.C. § 112. As noted above, one of ordinary skill in the art would understand that the originally claimed "stable lansoprazole" is a composition comprising lansoprazole, water and/or alcohol, and other trace impurities, and, thus, the presently claimed stable lansoprazole composition is fully supported by the application and claims, as originally filed.

Moreover, the Examiner's reliance on *In re Sus and Schaefer*, 134 USPQ 301 and *In re Cavallito and Gray*, 134 USPQ 370 as related to pure compounds and applied to the above rejection is misplaced. *In re Sus and Schaefer* dealt with the situation wherein a generic term in the claimed invention related to a class of compounds while the invention described in the specification was more narrow and related to a subset of this class of compounds. The generic term therefor was too broad and a different more specific term describing the organic compounds should have been used. Similarly, the term "lower aliphatic" as in the claims in *In re Cavallito and Gray* was not specific enough for the invention to "lower alkyl" and "lower alkenyl" compounds only. In both cases the issue was whether the claimed chemical term was commensurate the scope with the chemical compound of the invention whereas in the presently claimed invention the term "comprising" may be used to describe that a chemical entity such as lansoprazole may contain trace elements or some impurities. For these reasons, the claimed invention as in claims 1-7 and 29-38 is definite and clearly describes the claimed subject matter.

With regard to the recitation of the term "lansoprazole" in claims 1-7 and 29-38, the Examiner asserts that where the generic name lansoprazole is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with 35 U.S.C. § 112, second paragraph. The Examiner cites *Ex Parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). According to the Examiner the claim scope is uncertain since the generic

name cannot be used to properly identify any particular material or product. The Examiner asserts that a generic name is used to identify a source of goods, and not the goods themselves.

In response, Applicants submit that contrary to the Examiner's assertions a generic name of an active pharmaceutical ingredient does not identify a source of goods, but identifies the active pharmaceutical ingredient itself. The Examiner has confused the terms "generic name" and "trade name." A "trade name" identifies a source of goods. The term "lansoprazole" is not a trade name but a generic name for the chemical entity. Lansoprazole is an active pharmaceutical ingredient marketed under the trade name PREVACID in the United States. For this reason, *Ex Parte Simpson*, cited by the Examiner, does not apply as it relates to the use of trade names. Applicants submit that the term lansoprazole identifies an active pharmaceutical ingredient regardless of its source and therefore clearly identifies and describes the claimed subject matter in claims 1-7 and 29-38.

Therefore, the claims particularly point out and distinctly claim the subject matter Applicants regard as the invention. Accordingly, it is respectfully requested that the Examiner withdraw the rejection of claims 1 to 7 and 29 to 38 under 35 U.S.C. §112, second paragraph.

5. Claims 1-7 and 29-38 were provisionally rejected under the judicially created doctrine of obviousness type double patenting.

Claims 1-7 and 29-38 are provisionally rejected under the judicially created doctrine of obviousness type double patenting as being unpatentable over claims 33-38 and 42-45 of copending U.S. Application Ser No. 10/773,535 in view of Haleblian et al., Chemical & Engineering News, US Pharmacopeia, Muzaffar et al, Jain et al, Taday et al, and Concise Encyclopedia Chemistry. According to the Examiner the stable compound and compositions are disclosed in this copending application. In response, Applicants wish to defer filing a terminal disclaimer until the currently pending claims are deemed allowable, at which time, Applicants intend to file a terminal disclaimer.

Applicants thus submit that the entire application is now in condition for allowance, an early notice of which would be appreciated. Should the Examiner not agree with Applicants' position, a personal or telephonic interview is respectfully requested to discuss

any remaining issues prior to the issuance of a further Office Action, and to expedite the allowance of the application.

Respectfully submitted,

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